K121879

B. 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

JUL 27 2012

VEGA Knee System
June 20, 2012

COMPANY: Aesculap® Implant Systems, LLC
3773 Corporate Parkway
Center Valley, PA 18034

ESTABLISHMENT REGISTRATION NUMBER: 3005673311

CONTACT: Julie Tom Wing
610-984-9147 (phone)
610-791-6882 (fax)
Julie.TomWing@aesculap.com

DEVICE

TRADE NAME: VEGA Knee System

COMMON NAME: Total Knee System

DEVICE CLASS: CLASS II

PRODUCT CODE: JWH

REGULATION NUMBER: 888.3560

CLASSIFICATION NAME: Knee Joint Patellofemorotibial Polymer/Metal/Polymer Semi constrained Cemented Prosthesis

SUBSTANTIAL EQUIVALENCE

Aesculap Implant Systems, LLC believes that the modification to VEGA Knee System remain substantially equivalent to Aesculap Implant Systems VEGA Knee System originally cleared in 510(K) K101281.

DEVICE DESCRIPTION

The VEGA Knee System is a semi-constrained cemented prosthesis with a Posterior Stabilization (PS) design. The femoral component, tibial plateau and extension stem are manufactured from Cobalt Chromium Molybdenum alloy (CoCrMo) with a Zirconium nitride (ZrN) coating. The tibial "gliding surfaces" (inserts) and patella are manufactured from Ultra High Molecular Weight Polyethylene (UHMWPE) and the tibial plug is made of PEEK. The system is made up of numerous components available in various sizes. All components are sterile and for single use only.

K121879

INDICATIONS FOR USE

The VEGA Knee System is indicated for use in reconstruction of the diseased knee joint caused by osteoarthritis, rheumatoid arthritis, post-traumatic arthritis, the need to revise failed arthroplasties or osteotomies where pain, deformity or dysfunction persist, and for patients suffering from correctable valgus or varus deformity and moderate flexion contracture.

Posterior Stabilized (PS) components are also for absent or non-functioning posterior cruciate ligament and severe anteroposterior instability of the knee joint.

The VEGA Knee System is designed for use with bone cement.

TECHNOLOGICAL CHARACTERISTICS (Compared to the Predicate)

The entire VEGA Knee System was cleared under K101281. The fundamental scientific technology and materials for the VEGA system remain the same. The only difference is the design modification of wrench size to VEGA 10mm extension stems.

PERFORMANCE DATA

Mechanical testing of the Aesculap Implant Systems VEGA 10mm extension stems was performed as a result of the risk assessment.
The results were found to be similar to the legally marketed VEGA Knee System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Aesculap Implant Systems, LLC
% Ms. Julie Tom Wing
3773 Corporate Parkway
Center Valley, Pennsylvania 18034

JUL 27 2012

Re: K121879
Trade/Device Name: VEGA Knee System
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: JWH
Dated: June 26, 2012
Received: June 28, 2012

Dear Ms. Tom Wing:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

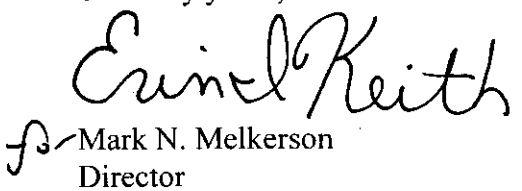
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

A. INDICATIONS FOR USE STATEMENT

510(k) Number: K121879

Device Name: VEGA Knee System

Indications for Use:

The VEGA Knee System is indicated for use in reconstruction of the diseased knee joint caused by osteoarthritis, rheumatoid arthritis, post-traumatic arthritis, the need to revise failed arthroplasties or osteotomies where pain, deformity or dysfunction persist, and for patients suffering from correctable valgus or varus deformity and moderate flexion contracture.

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(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K121879

Prescription Use X and/or Over-the-Counter Use _____

(per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)